

REMARKS

With entry of this amendment, claims 1-207 are pending in the application. Claims 68-95, 100-108 and 113-207 are withdrawn from consideration with traverse as being drawn to non-elected subject matter. Claims 1-67, 96-99 and 109-112 are examined on the merits.

Status of Restricted Claims

Applicants acknowledge their election with traverse of Group I, claims 1-67, 96-99 and 109-114. Applicants further acknowledge that the Office has re-designated claims as having to be withdrawn in view of the Restriction Requirement on the asserted basis that claims 113 and 114 were improperly included in Group I, and belong instead with Group II, designated as being drawn to an infectious recombinant RSV having a heterologous gene. Applicants do not accede to the merits of this re-assignment or the Office's designation of groups of "inventions" within the original claims, however the subject claims have been re-designated as withdrawn in the pending claims to advance the application to issuance. Finally, Applicants acknowledge that upon further consideration the Office has withdrawn the requirement to elect human or bovine polynucleotides from claim 6.

Specification

The abstract of the disclosure is objected to because it exceeds 150 words. Appropriate revisions have been made herein to comply with the Office's suggestion to limit the length of the Abstract.

Patentability Under 35 USC § 112, Second Paragraph

Claims 96-97 are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. The Office considers that the claims are drawn to a recombinant respiratory syncytial virus, and that claim 96 is redundant by reciting that the virus of claim 1 is a virus. With respect to claim 97, the Office contends that "[i]t is not clear how the virus of claim 1 can also be a subviral particle."

Applicants respectfully traverse this ground of rejection, but note that the rejection is rendered moot by the clarifying amendments and remarks relating to the subject claims, presented herein. In particular, the alleged lack of clarity has been resolved by amendment of claim 96 herein to recite that the claimed RSV is “a complete virus.” As is clearly denoted in the specification and original claims, the recombinant RSV of the invention is an infectious viral particle which comprises, at a minimum, the N, P, and L proteins and an RNA polymerase elongation factor (specified in the claims as amended herein to comprise an M2(ORF1) RNA polymerase elongation factor. As such, this basic virus particle is viable and infectious without the inclusion of non-essential components of a “complete” RSV. In contrast, as is also disclosed in the specification, it is within the scope of the invention to provide recombinant RSVs that comprise essentially complete viruses, i.e., with all essential viral components and further including non-essential components up to and including all components found, e.g., in a wild-type, RSV. Clearly representative of these teachings, the specification teaches that certain non-essential genes and/or genome segments, for example the SH, NS1, and NS2, genes, can be ablated or otherwise modified to yield desired effects on virulence, pathogenesis, immunogenicity and other phenotypic characters.

Accordingly, Applicants respectfully submit that there is no remaining lack of clarity or grounds for objection to form in the instant claims 96 and 97, considering that claim 96 now more clearly recites a “complete virus” as a dependent species within the scope of claim 1. Consistent with this terminology, the invention encompasses both complete viral particles and “subviral” particles (as recited in claim 97), the latter of which are disclosed in the specification and will be understood by the skilled artisan to encompass viable, infectious recombinant RSVs engineered to lack one or more non-essential components of a “complete” RSV. For these reasons, the rejection of claims 96-97 under 35 U.S.C. 112, second paragraph is believed to be obviated..

Patentability Under 35 USC § 112, First Paragraph

Claims 1-67,96-99 and 109-112 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter that is not sufficiently described and enabled by the specification. The Office acknowledges that the disclosure describes and enables

recombinant RSV comprising an M2 ORF 1 polymerase elongation factor, but asserts that the disclosure fails to support a generic class of recombinant RSVs comprising "any RNA polymerase elongation factor."

Applicants traverse the stated grounds for rejection but note that the rejection is obviated by the amendment herein to the claims—specifically reciting "a M2 (ORF1) RNA polymerase elongation factor" as exemplary subject matter within the indicated aspect of the invention. The Office has expressly recognized enabling support for this subject matter in the application, therefore withdrawal of the rejection of claims 1-67, 96-99 and 109-112 under 35 U.S.C. 112, first paragraph is earnestly solicited.

Patentability Under 35 USC § 103

Claims 1-67, 96-99 and 109-112 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Collins (6,264,957) in view of Ball *et al* (J: *Viol.*, 1999,73:4705-4712). Collins is cited for allegedly teaching isolated, infectious recombinant RSV comprising proteins N, P, L, a RNA polymerase elongation factor (M2-ORF1), and a partial or complete recombinant RSV genome or antigenome. The Office further relies on Collins for teaching modifications (e.g., rearrangements, deletions, substitutions and insertions) to recombinant RSV to produce desired phenotypic changes, such as attenuation, and using these recombinant RSVs in immunogenic compositions. Ball is relied upon for allegedly disclosing rearrangements of P, M and G genes of Vesicular Stomatitis virus (VSV) resulting in viable, infectious viruses. Based on the combined teachings of the cited references, the Office contends that it would have been "obvious to make the rearrangements suggested by Ball to achieve desired phenotypes", and that there would have been "a reasonable expectation of success that the rearrangements for VSV would have been successful in RSV because gene order between nonsegmented negative-strand RNA viruses is highly conserved."

Applicants respectfully traverse the foregoing grounds of rejection on the following bases.

To begin with, the cited Collins reference has a common inventor with the instant application and is believed to constitute prior art only under 35 U.S.C. 102(e), as kindly noted by the Office. Because the instant application was filed on or after November 29, 1999, the rejection can be overcome by showing that the subject matter of the reference

and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person (see MPEP § 706.02(1)(1) and § 706.02(1)(2). In this context, MPEP 706.02(1)(2) provides that: "Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person."

Statement Regarding Common Ownership and Obligation of Assignment

Applicants, through their undersigned representative, hereby confirm that the instant application and the above-cited Collins patent (USPN 6,264,957) were owned by, or subject to an obligation of assignment to the same person, at the time each of the respective inventions were made.

Although the current rejection over Collins '957 in view of Ball is considered to be obviated in view of the foregoing statement of common ownership, Applicants note that there is a counterpart PCT publication to the '957 patent. Specifically, parallel PCT case PCT/US96/15524 filed September 27, 1996, claiming priority to the same US Provisional application (serial number 60/007,083, filed September 27, 1995) as the instant application, published as WO 97/12032 on April 04, 1997. Therefore, the subject reference is submitted for the Office's consideration as part of Applicants' information disclosure obligation, and will be formally presented in a Supplemental Information Disclosure Statement to be filed under separate cover.

For the Office's further consideration, Applicants provide reference herein to two additional patents that may be relevant to the Office's review of the instant application. In particular, Ball et al., U.S. Patent No. 6,136,585, issued July 22, 2003, and Wertz et al., U.S. Patent No. 6,596,529, issued October 24, 2000, each provide reports pertaining to gene shuffling in mononegaviruses. These references are also submitted for the Office's consideration as part of Applicants' information disclosure obligation, and will

be formally presented in a Supplemental Information Disclosure Statement to be filed under separate cover

Irrespective of the status of the cited Collins patent (6,264,957) under 35 USC § 103(c), and even considering the disclosures set forth in the counterpart Collins PCT publication WO 97/12032 and the above-noted Ball et al. '585 and Wertz et al. '529 patents, the subject matter of the pending claims is respectfully considered to be allowable over all art of record. With respect to the Collins '957 patent, this patent matured from the same lineage from which the current application now enjoys priority, as amended herein above. The amended priority thus presented relates back through two separate lineages having extant pending U.S. applications from which copendency presently extends, to earliest respective lineage members U.S. Provisional Application 60/021,773, filed July 15, 1996, and U.S. Provisional Application No. 60/007,083, filed September 27, 1995. Therefore any issues pertaining to the Collins '957 patent are expected to be limited to possible double patenting issues, and appropriate clarification by the Office on this subject is respectfully requested. With respect to the Ball et al. '585 and Wertz et al. '529 patents, these patents specify earliest claimed priority dates stemming from the same U.S. Provisional Application No. 60/045,471, filed May 02, 1997. Accordingly, to the extent these references might disclose information pertaining to the presently claimed subject matter, Applicants respectfully submit that the instant application enjoys priority of disclosure for said subject matter. The same priority analysis is believed to apply to the Ball et al. (J: *Viol.*, 1999,73:4705-4712) reference cited by the Office as a secondary reference in combination with the Collins '957 patent. The subject matter of this reference, to the extent it may pertain to subject matter set forth in the currently pending claims, is obviated as a basis for a statutory claim rejection based on Applicants' amended priority claim.

Double Patenting

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness- type double patenting as allegedly unpatentable over claim 9 of copending Application No. 09/602,212. The Office contends that, although the conflicting claims are not identical, they are allegedly not patentably distinct from each other because the instant claim is drawn to an infectious, recombinant RSV comprising a RSV genome

having shifted genes. Claim 9 of the copending application is characterized by the Office as being drawn to an infectious, recombinant, chimeric (human and bovine) RSV comprising a RSV genome having shifted genes, and on this basis claim 9 is characterized as "a species of claim 1".

Claims 1, 2, 8 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 9-10 of copending Application No. 09/611,829 in view of Collins (6,264,957). Collins '957 is relied upon as noted above.

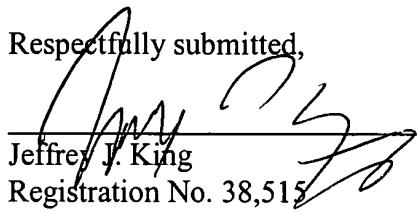
With respect to both double patenting rejections, Applicants note the provisionality of the rejections and respectfully decline to address the merits of the rejections until allowable subject matter is indicated in one of the allegedly conflicting applications, at which time appropriate action will be taken. Concerning the second rejection over copending Application No. 09/611,829 in view of Collins (6,264,957), the Collins '957 patent is believed to be overcome as prior art as noted above, although consideration of the newly-submitted art of record (to be formalized by submission of a Supplemental Information Disclosure Statement), discussed above, is requested in the event double patenting issues are maintained in the application.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (425) 455-5575.

Date: August 20, 2003

Respectfully submitted,



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